

## MEDICAL POLICY – 8.03.01

## Functional Neuromuscular Electrical Stimulation

BCBSA Ref. Policy: 8.03.01

Effective Date: June 1, 2024

Last Revised: May 13, 2024

Replaces: N/A

## RELATED MEDICAL POLICIES:

1.01.507 Electrical Stimulation Devices

1.03.04 Powered Exoskeleton for Ambulation in Patients With Lower-Limb Disabilities


1.04.502 Myoelectric Prosthetic and Orthotic Components for the Upper Limb

1.04.503 Microprocessor-Controlled Prostheses for the Lower Limb

7.01.69 Sacral Nerve Neuromodulation/Stimulation

Select a hyperlink below to be directed to that section.

[POLICY CRITERIA](#) | [CODING](#) | [RELATED INFORMATION](#)  
[EVIDENCE REVIEW](#) | [REFERENCES](#) | [HISTORY](#)

 Clicking this icon returns you to the hyperlinks menu above.

## Introduction

To move a muscle, the brain sends an electrical signal. The signal travels along the nerve to the muscle fibers. When the muscle fibers receive the signal, they move. Instead of the electrical signals coming from the brain, functional neuromuscular electrical stimulation sends electricity to the muscles through an external power source. The signals arise from a microprocessor and flow to electrodes that are placed on the skin with a patch or implanted. The electrical signals stimulate the targeted nerves to create muscle contractions. This technique has been proposed as a way to try to bring back muscle function after illness, injury, or surgery. It has also been proposed to strengthen muscles that haven't been used for some time. There is not enough evidence in the medical studies published to date to show how well this proposed treatment works. For this reason, it's considered investigational (unproven).

**Note:** The Introduction section is for your general knowledge and is not to be taken as policy coverage criteria. The rest of the policy uses specific words and concepts familiar to medical professionals. It is intended for providers. A provider can be a person, such as a doctor, nurse, psychologist, or dentist. A provider also can be a place where medical care is given, like a hospital, clinic, or lab. This policy informs them about when a service may be covered.

## Policy Coverage Criteria

Procedure	Investigational
<b>Neuromuscular stimulation</b>	<p><b>Neuromuscular stimulation is considered investigational as a technique to restore function following nerve damage or nerve injury. This includes its use in the following situations:</b></p> <ul style="list-style-type: none"> <li>• As a technique to provide ambulation in individuals with spinal cord injury (SCI)</li> <li>• To provide upper extremity function in individuals with nerve damage (e.g., SCI or post-stroke)</li> <li>• To improve ambulation in individuals with foot-drop caused by congenital disorders (e.g., cerebral palsy) or nerve damage (e.g., post-stroke or in those with multiple sclerosis)</li> </ul> <p><b>Functional electrical stimulation devices for exercise in individuals with spinal cord injury is considered investigational (see <a href="#">Benefit Application</a>).</b></p>

## Coding

Code	Description
<b>HCPCS</b>	
E0764	Functional neuromuscular stimulation, transcutaneous stimulation of sequential muscle groups of ambulation with computer control, used for walking by spinal cord injured, entire system, after completion of training program (such as the ParaStep - an ambulation aid for patients with spinal cord injury)
E0770	Functional electrical stimulator, transcutaneous stimulation of nerve and/or muscle groups, any type, complete system, not otherwise specified (such as stimulators used in patients with footdrop)

**Note:** CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). HCPCS codes, descriptions and materials are copyrighted by Centers for Medicare Services (CMS).

## Related Information



## Benefit Application

Functional electrical stimulation (FES) devices including but not limited to the following are considered home exercise equipment: ERGYS (leg cycle ergometer), REGYS (leg cycle RT200 Elliptical, RT300 RES cycle ergometer (also referred to as FES bicycle), StimMaster Galaxy (FES exercise bike) or the RT600 Step and Stand Rehabilitation Therapy System for stationary exercise.

The Company considers FES devices to be home exercise equipment. Most contract plans exclude coverage of exercise equipment for use in the home. Please refer to the member's contract language for details.

## Evidence Review

---

### Description

Functional electrical stimulation (FES) involves the use of an orthotic device or exercise equipment with microprocessor-controlled electrical muscular stimulation. These devices are being developed to restore function and improve health in individuals with damaged or destroyed nerve pathways (e.g., spinal cord injury (SCI), stroke, multiple sclerosis, cerebral palsy).

### Background

#### Functional Electrical Stimulation

FES is an approach to rehabilitation that applies low-level electrical current to stimulate functional movements in muscles affected by nerve damage. It focuses on the restoration of useful movements, like standing, stepping, pedaling for exercise, reaching, or grasping.

FES devices consist of an orthotic and a microprocessor-based electronic stimulator with one or more channels for delivery of individual pulses through surface or implanted electrodes connected to the neuromuscular system. Microprocessor programs activate the channels sequentially or in unison to stimulate peripheral nerves and trigger muscle contractions to produce functionally useful movements that allow individuals to sit, stand, walk, cycle, or grasp.



Functional neuromuscular stimulators are closed-loop systems that provide feedback information on muscle force and joint position, thus allowing constant modification of stimulation parameters, which are required for complex activities (e.g., walking). These systems are contrasted with open-loop systems, which are used for simple tasks (e.g., muscle strengthening alone); healthy individuals with intact neural control benefit the most from this technology.

Applications include upper-extremity grasping function after SCI and stroke, lifting the front of the foot during ambulation in individuals with footdrop, ambulation, and exercise for individuals with SCI. Some devices are used primarily for rehabilitation rather than home use. This policy focuses on devices intended for home use.

## Summary of Evidence

For individuals who have loss of hand and upper-extremity function due to SCI or stroke who receive FES, the evidence includes a few small case series and a randomized controlled trial (RCT). The relevant outcomes are functional outcomes and quality of life. Interpretation of the evidence is limited by the low number of individuals studied and lack of data demonstrating the utility of FES outside the investigational setting. It is uncertain whether FES can restore some upper-extremity function or improve quality of life. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have chronic footdrop who receive FES, the evidence includes RCTs, meta-analyses, and a longitudinal cohort study. The relevant outcomes are functional outcomes and quality of life. For chronic poststroke footdrop, two RCTs comparing FES with a standard ankle-foot orthosis (AFO) showed improved individual satisfaction with FES, but no significant difference between groups in objective measures such as walking. Another RCT found no significant differences between use versus no use of FES on walking outcomes. Similarly, one meta-analysis found no difference between AFO and FES in walking speed, and another meta-analysis found no difference between FES and conventional treatments. The cohort study assessed individuals' ability to avoid obstacles while walking on a treadmill using FES versus AFO. Although the FES group averaged a 4.7% higher rate of avoidance, the individual results between devices ranged widely. One RCT with 53 subjects examining neuromuscular stimulation for foot drop in individuals with multiple sclerosis showed a reduction in falls and improved individual satisfaction compared with an exercise program but did not demonstrate a clinically significant benefit in walking speed. Another RCT showed that at 12 months, both FES and AFO had improved walking speed, but the difference in improvement between the two devices was not significant. Another study found FES (combined with postural correction) and



neuroproprioceptive facilitation and inhibition physiotherapy did not differ in walking speed or balance immediately or two months after program end. A reduction in falls is an important health outcome. However, it was not a primary study outcome and should be corroborated. The literature on FES in children with cerebral palsy includes 3 systematic reviews of small studies with within-subject designs. All included studies only measure short-term results; it is unclear what the long-term effects of FES may be in this population. Further study is needed. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have SCI at segments T4 to T12 who receive FES, the evidence includes case series. The relevant outcomes are functional outcomes and quality of life. No controlled trials were identified on FES for standing and walking in individuals with SCI. However, case series are considered adequate for this condition because there is no chance for unaided ambulation in this population with SCI at this level. Some studies have reported improvements in intermediate outcomes, but improvement in health outcomes (e.g., ability to perform activities of daily living [ADL], quality of life) have not been demonstrated. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.

For individuals who have SCI who receive FES exercise equipment, the evidence includes prospective comparisons. The relevant outcomes are symptoms, functional outcomes, and quality of life. The evidence on FES exercise equipment consists primarily of within-subject, pre- to post-treatment comparisons. Evidence was identified on two commercially available FES cycle ergometer models for the home, the RT300 series and the REGYS/ERGYS series. There is a limited evidence on the RT300 series. None of the within-subject studies showed an improvement in health benefits however, improvement in body fat with RT300 was found in a small group of individuals when FES high intensity interval cycling was added to nutrition counseling compared to nutritional counseling alone. One analysis of use for 314 individuals over 20,000 activity sessions with a Restorative Therapeutics device showed that a majority of users used the device for 34 minutes per week. Two percent of individuals with SCI used the device for an average of six days per week, but caloric expenditure remained low. Compliance was shown in one study to be affected by the age of participants and level of activity prior to the study. Studies on the REGYS/ERGYS series have more uniformly shown an improvement in physiologic measures of health and in sensory and motor function; however, a small comparative study found arm cycling to improve exercise energy expenditure and cardiorespiratory fitness to a greater extent than FES leg cycling. A limitation of these studies is that they all appear to have been conducted in supervised research centers. No studies were identified on long-term home use of ERGYS cycle ergometers. The feasibility and long-term health benefits of using this device in the home is uncertain. The evidence is insufficient to determine that the technology results in an improvement in the net health outcome.



## Ongoing and Unpublished Clinical Trials

Some currently ongoing and unpublished trials that might influence this policy are listed in [Table 1](#).

**Table 1. Summary of Key Trials**

NCT No.	Trial Name	Planned Enrollment	Completion Date
<b>Ongoing</b>			
<a href="#">NCT03949387</a>	Functional Electrical Stimulation Cycling for Managing Mobility Disability in People With Multiple Sclerosis	40	Dec 2024
<a href="#">NCT03410498</a>	The Orthotic Effect of Functional Electrical Stimulation to Treat Foot Drop in People With MS Under Walking Conditions Simulating Those in Daily Life	20	Dec 2024
<a href="#">NCT04945395</a>	The Effect of Using Functional Electric Stimulation for the Recovery of Dorsiflexion During Rehabilitation of Gait Function, in the Subacute Phase After Stroke- a Randomized Controlled Exploratory Study	20	Feb 2024
<a href="#">NCT03495986</a>	Spinal Cord Injury Exercise and Nutrition Conceptual Engagement (SCIENCE)	60	May 2024
<a href="#">NCT00583804</a>	Implanted Myoelectric Control for Restoration of Hand Function in Spinal Cord Injury	10 (actual)	Jan 2026
<b>Unpublished</b>			
<a href="#">NCT00890916</a>	Hand Function for Tetraplegia Using a Wireless Neuroprosthesis	10	May 2021
<a href="#">NCT03385005</a>	Evaluating Neuromuscular Stimulation for Restoring Hand Movements	8	Jun 2023

NCT: national clinical trial.

## Practice Guidelines and Position Statements

The purpose of the following information is to provide reference material. Inclusion does not imply endorsement or alignment with the policy conclusions.



Guidelines or position statements will be considered for inclusion if they were issued by, or jointly by, a US professional society, an international society with US representation, or National Institute for Health and Care Excellence (NICE). Priority will be given to guidelines that are informed by a systematic review, include strength of evidence ratings, and include a description of management of conflict of interest.

## **National Institute for Health and Care Excellence**

In 2009, NICE published guidance stating that the evidence on FES for footdrop of neurologic origin appeared adequate to support its use.<sup>47</sup> The Institute noted that patient selection should involve a multidisciplinary team. The Institute advised that further publication on the efficacy of functional electrical stimulation would be useful, specifically including patient-reported outcomes (e.g., quality of life, activities of daily living) and these outcomes should be examined in different ethnic and socioeconomic groups.

## **Medicare National Coverage**

Medicare (2002 updated in 2006) issued a national coverage policy recommending coverage for neuromuscular electrical stimulation (NMES) for ambulation in SCI patients consistent with the US Food and Drug Administration (FDA) labeling for the Parastep device.<sup>1,48</sup> The Medicare decision memorandum indicates that Medicare considered the same data as those discussed herein in their decision-making process. The decision memorandum noted that the available studies were flawed but concluded that the limited ambulation provided by the Parastep device supported its clinical effectiveness and thus its coverage eligibility. The inclusion criteria outlined by Medicare are as follows:

1. Persons with intact lower motor units (L1 and below)
2. Persons with muscle and joint stability for weight bearing at upper and lower extremities that can demonstrate balance and control to maintain an upright support posture independently
3. Persons who demonstrate brisk muscle contraction to NMES and have sensory perception of electrical stimulation sufficient for muscle contraction
4. Persons who possess high motivation, commitment, and cognitive ability to use such devices for walking



5. Persons who can transfer independently and can demonstrate standing tolerance for at least 3 minutes
6. Persons who can demonstrate hand and finger function to manipulate controls
7. Persons with at least 6-month post recovery SCI and restorative surgery
8. Persons without hip and knee degenerative disease and no history of long bone fracture secondary to osteoporosis
9. Persons who have demonstrated a willingness to use the device long-term

The exclusion criteria are as follows:

1. Persons with cardiac pacemakers
2. Severe scoliosis or severe osteoporosis
3. Skin disease or cancer at area of stimulation
4. Irreversible contracture
5. Autonomic dysreflexia

## Regulatory Status

A variety of FES devices have been cleared by the US Food and Drug Administration (FDA) and are available for home use. **Table 2** provides examples of devices designed to improve hand and foot function as well as cycle ergometers for home exercise. The date of the FDA clearance is for the first 510(k) clearance identified for a marketed device. Many devices have additional FDA clearances as the technology evolved, each in turn listing the most recent device as the predicate.

**Table 2. Functional Electrical Stimulation Devices Cleared by the FDA**

Device	Manufacturer	Device Type	Clearance	Date	Product Code
NESS H200 (previously Handmaster)	Bioness	Hand stimulator	K022776	2001	GZI





Device	Manufacturer	Device Type	Clearance	Date	Product Code
MyndMove System	MyndTec	Hand stimulator	K170564	2017	GZI/IPF
ReGrasp	Rehabtronics	Hand stimulator	K153163	2016	GZI/IPF
WalkAide System	Innovative Neurotronics (formerly NeuroMotion)	Foot drop stimulator	K052329	2005	GZI
ODFS (Odstock Dropped Foot Stimulator)	Odstock Medical	Foot drop stimulator	K050991	2005	GZI
ODFS Pace XL	Odstock Medical	Foot drop stimulator	K171396	2018	GZI/IPF
L300 Go	Bioness	Foot drop stimulator	K190285	2019	GZI/IPF
L100 Go	Bioness	Foot drop stimulator	K200262	2020	GZI/IPF
Foot Drop System	SHENZHEN XFT Medical	Foot drop stimulator	K162718	2017	GZI
Nerve And Muscle Stimulator	SHENZHEN XFT Medical	Foot drop stimulator	K193276	2020	GZI
MyGait Stimulation System	Otto Bock HealthCare	Foot drop stimulator	K141812	2015	GZI
MStim Drop Model LGT-233	Guangzhou Longest Science & Technology	Foot drop stimulator	K202110	2021	GZI/IPF
ERGYS (TTI Rehabilitation Gym)	Therapeutic Alliances	Leg cycle ergometer	K841112	1984	IPF
RT300	Restorative Therapies, Inc (RTI)	Cycle ergometer	K050036	2005	GZI
Myocycle Home	Myolyn	Cycle ergometer	K170132	2017	GZI
Cionic Neural Sleeve NS-100	Cionic	Foot drop stimulator	K221823	2022	GZI/IPF
EvoWalk 1.0	Evolution Devices Inc	Foot drop stimulator	K230997	2023	GZI

FDA: US Food and Drug Administration.

To date, the Parastep Ambulation System (Sigmedics) is the only noninvasive functional walking neuromuscular stimulation device to receive premarket approval from the FDA. The Parastep



device is approved to “enable appropriately selected skeletally mature spinal cord injured patients (level C6-T12) to stand and attain limited ambulation and/or take steps, with assistance if required, following a prescribed period of physical therapy training in conjunction with rehabilitation management of SCI.”<sup>1</sup>

FDA product code: MKD.

## References

1. Centers for Medicare & Medicaid Services. Decision Memo for Neuromuscular Electrical Stimulation (NMES) for Spinal Cord Injury (CAG-00153R). 2002; <https://www.cms.gov/medicare-coverage-database/details/nca-decision-memo.aspx?NCAId=55>. Accessed April 4, 2024.
2. Mulcahey MJ, Betz RR, Kozin SH, et al. Implantation of the Freehand System during initial rehabilitation using minimally invasive techniques. *Spinal Cord*. Mar 2004; 42(3): 146-55. PMID 15001979
3. Mulcahey MJ, Betz RR, Smith BT, et al. Implanted functional electrical stimulation hand system in adolescents with spinal injuries: an evaluation. *Arch Phys Med Rehabil*. Jun 1997; 78(6): 597-607. PMID 9196467
4. Taylor P, Esnouf J, Hobby J. The functional impact of the Freehand System on tetraplegic hand function. *Clinical Results. Spinal Cord*. Nov 2002; 40(11): 560-6. PMID 12411963
5. Venugopalan L, Taylor PN, Cobb JE, et al. Upper limb functional electrical stimulation devices and their man-machine interfaces. *J Med Eng Technol*. 2015; 39(8): 471-9. PMID 26508077
6. Alon G, McBride K. Persons with C5 or C6 tetraplegia achieve selected functional gains using a neuroprosthesis. *Arch Phys Med Rehabil*. Jan 2003; 84(1): 119-24. PMID 12589632
7. Alon G, McBride K, Ring H. Improving selected hand functions using a noninvasive neuroprosthesis in persons with chronic stroke. *J Stroke Cerebrovasc Dis*. 2002; 11(2): 99-106. PMID 17903863
8. Snoek GJ, IJzerman MJ, in 't Groen FA, et al. Use of the NESS handmaster to restore handfunction in tetraplegia: clinical experiences in ten patients. *Spinal Cord*. Apr 2000; 38(4): 244-9. PMID 10822395
9. Anderson KD, Korupolu R, Musselman KE, et al. Multi-center, single-blind randomized controlled trial comparing functional electrical stimulation therapy to conventional therapy in incomplete tetraplegia. *Front Rehabil Sci*. 2022; 3: 995244. PMID 36188946
10. Jaqueline da Cunha M, Rech KD, Salazar AP, et al. Functional electrical stimulation of the peroneal nerve improves post-stroke gait speed when combined with physiotherapy. A systematic review and meta-analysis. *Ann Phys Rehabil Med*. Jan 2021; 64(1): 101388. PMID 32376404
11. Nascimento LR, da Silva LA, Araújo Barcellos JVM, et al. Ankle-foot orthoses and continuous functional electrical stimulation improve walking speed after stroke: a systematic review and meta-analyses of randomized controlled trials. *Physiotherapy*. Dec 2020; 109: 43-53. PMID 33120054
12. Hachisuka K, Ochi M, Kikuchi T, et al. Clinical effectiveness of peroneal nerve functional electrical stimulation in chronic stroke patients with hemiplegia (PLEASURE): A multicentre, prospective, randomised controlled trial. *Clin Rehabil*. Mar 2021; 35(3): 367-377. PMID 33103916



13. Bethoux F, Rogers HL, Nolan KJ, et al. The effects of peroneal nerve functional electrical stimulation versus ankle-foot orthosis in patients with chronic stroke: a randomized controlled trial. *Neurorehabil Neural Repair*. Sep 2014; 28(7): 688-97. PMID 24526708
14. Kluding PM, Dunning K, O'Dell MW, et al. Foot drop stimulation versus ankle foot orthosis after stroke: 30-week outcomes. *Stroke*. Jun 2013; 44(6): 1660-9. PMID 23640829
15. O'Dell MW, Dunning K, Kluding P, et al. Response and prediction of improvement in gait speed from functional electrical stimulation in persons with poststroke drop foot. *PM R*. Jul 2014; 6(7): 587-601; quiz 601. PMID 24412265
16. Berenpas F, Geurts AC, den Boer J, et al. Surplus value of implanted peroneal functional electrical stimulation over ankle-foot orthosis for gait adaptability in people with foot drop after stroke. *Gait Posture*. Jun 2019; 71: 157-162. PMID 31071538
17. Prokopiusova T, Pavlikova M, Markova M, et al. Randomized comparison of functional electric stimulation in posturally corrected position and motor program activating therapy: treating foot drop in people with multiple sclerosis. *Eur J Phys Rehabil Med*. Aug 2020; 56(4): 394-402. PMID 32383574
18. Renfrew LM, Paul L, McFadyen A, et al. The clinical- and cost-effectiveness of functional electrical stimulation and ankle-foot orthoses for foot drop in Multiple Sclerosis: a multicentre randomized trial. *Clin Rehabil*. Jul 2019; 33(7): 1150-1162. PMID 30974955
19. Barrett CL, Mann GE, Taylor PN, et al. A randomized trial to investigate the effects of functional electrical stimulation and therapeutic exercise on walking performance for people with multiple sclerosis. *Mult Scler*. Apr 2009; 15(4): 493-504. PMID 19282417
20. Esnouf JE, Taylor PN, Mann GE, et al. Impact on activities of daily living using a functional electrical stimulation device to improve dropped foot in people with multiple sclerosis, measured by the Canadian Occupational Performance Measure. *Mult Scler*. Sep 2010; 16(9): 1141-7. PMID 20601398
21. Cauraugh JH, Naik SK, Hsu WH, et al. Children with cerebral palsy: a systematic review and meta-analysis on gait and electrical stimulation. *Clin Rehabil*. Nov 2010; 24(11): 963-78. PMID 20685722
22. Zhu Q, Gao G, Wang K, et al. Effect of Functional Electrical Stimulation on Gait Parameters in Children with Cerebral Palsy: A Meta-Analysis. *Comput Math Methods Med*. 2022; 2022: 3972958. PMID 36238472
23. Chen YH, Wang HY, Liao CD, et al. Effectiveness of neuromuscular electrical stimulation in improving mobility in children with cerebral palsy: A systematic review and meta-analysis of randomized controlled trials. *Clin Rehabil*. Jan 2023; 37(1): 3-16. PMID 35730135
24. Chaplin E. Functional neuromuscular stimulation for mobility in people with spinal cord injuries. The Parastep I System. *J Spinal Cord Med*. Apr 1996; 19(2): 99-105. PMID 8732878
25. Klose KJ, Jacobs PL, Broton JG, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 1. Ambulation performance and anthropometric measures. *Arch Phys Med Rehabil*. Aug 1997; 78(8): 789-93. PMID 9344294
26. Jacobs PL, Nash MS, Klose KJ, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 2. Effects on physiological responses to peak arm ergometry. *Arch Phys Med Rehabil*. Aug 1997; 78(8): 794-8. PMID 9344295
27. Needham-Shropshire BM, Broton JG, Klose KJ, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 3. Lack of effect on bone mineral density. *Arch Phys Med Rehabil*. Aug 1997; 78(8): 799-803. PMID 9344296
28. Guest RS, Klose KJ, Needham-Shropshire BM, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 4. Effect on physical self-concept and depression. *Arch Phys Med Rehabil*. Aug 1997; 78(8): 804-7. PMID 9344297



29. Nash MS, Jacobs PL, Montalvo BM, et al. Evaluation of a training program for persons with SCI paraplegia using the Parastep 1 ambulation system: part 5. Lower extremity blood flow and hyperemic responses to occlusion are augmented by ambulation training. *Arch Phys Med Rehabil.* Aug 1997; 78(8): 808-14. PMID 9344298
30. Graupe D, Kohn KH. Functional neuromuscular stimulator for short-distance ambulation by certain thoracic-level spinal-cord-injured paraplegics. *Surg Neurol.* Sep 1998; 50(3): 202-7. PMID 9736079
31. Brissot R, Gallien P, Le Bot MP, et al. Clinical experience with functional electrical stimulation-assisted gait with Parastep in spinal cord-injured patients. *Spine (Phila Pa 1976).* Feb 15 2000; 25(4): 501-8. PMID 10707398
32. Sykes L, Ross ER, Powell ES, et al. Objective measurement of use of the reciprocating gait orthosis (RGO) and the electrically augmented RGO in adult patients with spinal cord lesions. *Prosthet Orthot Int.* Dec 1996; 20(3): 182-90. PMID 8985998
33. Davis JA, Triolo RJ, Uhlir J, et al. Preliminary performance of a surgically implanted neuroprosthesis for standing and transfers--where do we stand?. *J Rehabil Res Dev.* 2001; 38(6): 609-17. PMID 11767968
34. Rohde LM, Bonder BR, Triolo RJ. Exploratory study of perceived quality of life with implanted standing neuroprostheses. *J Rehabil Res Dev.* 2012; 49(2): 265-78. PMID 22773528
35. Triolo RJ, Bailey SN, Miller ME, et al. Longitudinal performance of a surgically implanted neuroprosthesis for lower-extremity exercise, standing, and transfers after spinal cord injury. *Arch Phys Med Rehabil.* May 2012; 93(5): 896-904. PMID 22541312
36. U.S. Department of Health and Human Services Office of Disease Prevention and Health Promotion. Physical activity guidelines, second edition. <https://health.gov/paguidelines/second-edition/>. Accessed April 4, 2024.
37. Hunt KJ, Fang J, Saengsuwan J, et al. On the efficiency of FES cycling: a framework and systematic review. *Technol Health Care.* 2012; 20(5): 395-422. PMID 23079945
38. Ralston KE, Harvey L, Batty J, et al. Functional electrical stimulation cycling has no clear effect on urine output, lower limb swelling, and spasticity in people with spinal cord injury: a randomised cross-over trial. *J Physiother.* Dec 2013; 59(4): 237-43. PMID 24287217
39. Dolbow DR, Gorgey AS, Ketchum JM, et al. Home-based functional electrical stimulation cycling enhances quality of life in individuals with spinal cord injury. *Top Spinal Cord Inj Rehabil.* 2013; 19(4): 324-9. PMID 24244097
40. Dolbow DR, Gorgey AS, Ketchum JM, et al. Exercise adherence during home-based functional electrical stimulation cycling by individuals with spinal cord injury. *Am J Phys Med Rehabil.* Nov 2012; 91(11): 922-30. PMID 23085704
41. Johnston TE, Smith BT, Mulcahey MJ, et al. A randomized controlled trial on the effects of cycling with and without electrical stimulation on cardiorespiratory and vascular health in children with spinal cord injury. *Arch Phys Med Rehabil.* Aug 2009; 90(8): 1379-88. PMID 19651272
42. Dolbow DR, Credeur DP, Lemacks JL, et al. Electrically induced cycling and nutritional counseling for counteracting obesity after spinal cord injury: A pilot study. *J Spinal Cord Med.* Jul 2021; 44(4): 533-540. PMID 31971487
43. Sadowsky CL, Hammond ER, Strohl AB, et al. Lower extremity functional electrical stimulation cycling promotes physical and functional recovery in chronic spinal cord injury. *J Spinal Cord Med.* Nov 2013; 36(6): 623-31. PMID 24094120
44. Griffin L, Decker MJ, Hwang JY, et al. Functional electrical stimulation cycling improves body composition, metabolic and neural factors in persons with spinal cord injury. *J Electromyogr Kinesiol.* Aug 2009; 19(4): 614-22. PMID 18440241
45. Farkas GJ, Gorgey AS, Dolbow DR, et al. Energy Expenditure, Cardiorespiratory Fitness, and Body Composition Following Arm Cycling or Functional Electrical Stimulation Exercises in Spinal Cord Injury: A 16-Week Randomized Controlled Trial. *Top Spinal Cord Inj Rehabil.* 2021; 27(1): 121-134. PMID 33814890
46. Kressler J, Ghersin H, Nash MS. Use of functional electrical stimulation cycle ergometers by individuals with spinal cord injury. *Top Spinal Cord Inj Rehabil.* 2014; 20(2): 123-6. PMID 25477734
47. National Institute for Health and Care Excellence (NICE). Functional electrical stimulation for drop foot of central neurological origin [IPG278]. 2009; <http://www.nice.org.uk/nicemedia/pdf/IPG278Guidance.pdf>. Accessed April 4, 2024.



48. Centers for Medicare & Medicaid Services. National Coverage Determination (NCD) for Neuromuscular Electrical Stimulaton (NMES) (160.12). 2006; <https://www.cms.gov/medicare-coverage-database/details/ncd-details.aspx?NCDId=175&ncdver=2&DocID=160.12&SearchType=Advanced&bc=IAAABAAAA&>. Accessed April 4, 2024.

## History

Date	Comments
01/97	Add to Therapy Section - New Policy
06/27/00	Replace Policy - Policy revised to focus on ambulation.
05/13/03	Replace Policy - Literature review update; added to Rationale/Source section; No change in policy statement.
06/08/04	Replace Policy - Policy updated; no change in policy statement.
08/09/05	Replace Policy - Policy reviewed with literature search; no new clinical trials found. Policy statement unchanged.
02/06/06	Codes updated - No other changes.
06/23/06	Update Scope and Disclaimer - No other changes.
12/11/07	Replace Policy - Policy updated with literature review; policy statement clarified to include: "ambulation in patients with spinal cord injury and post-stroke" as investigational. References added.
06/09/09	Replace Policy - Policy updated with literature search. Policy statements modified to add a second policy statement that use of these devices in post-stroke patients is considered investigational. References added.
10/13/09	Replace Policy - Policy extensively updated with literature search. Additional applications added to policy statement (hand and foot). Title updated to Functional neuromuscular electrical stimulation. References updated.
03/08/11	Replace Policy - Policy updated with literature review; references added and reordered. Policy statement remains unchanged.
04/25/12	Replace policy. Policy updated with literature review through December 2011; reference 25 added; policy statement unchanged.
10/09/12	Update Coding Section – ICD-10 codes are now effective 10/01/2014.
04/08/13	Replace policy. Policy updated with literature review through January 16, 2013; references 11-12 and 29-31 added; cerebral palsy added to investigational policy statement.
06/14/13	Update Related Policies. Change title for 7.01.69 to "Sacral Nerve Neuromodulation/Stimulation".



Date	Comments
09/09/13	Clarification note added. This policy does not apply to specialized exercise equipment, such as the RT 300 Exercycle, that is used in the rehabilitation setting under the supervision of a physical therapist or other rehab specialist. Please refer to medical policy 8.03.502.
12/19/13	Update Related Policies. Remove 1.01.19 as it was archived.
05/05/14	Annual Review. Policy updated with literature review January 7, 2014. References 20 and 21 added; others renumbered/removed. Policy statement unchanged. All codes removed from policy with the exception of HCPCS codes; these are the only code utilized for adjudication.
06/27/14	Update Related Policies. Change title to 1.01.17.
04/24/15	Annual Review. Policy updated with literature review through January 16, 2015; references 20 and 22 added; policy statement unchanged. Clarification notes in policy statements retained.
08/28/15	Update Related Policies. Remove 1.01.17 and 8.01.39 as they were archived.
11/19/15	Update related policies. Remove 7.01.522.
07/01/16	Annual Review, approved June 14, 2016. Literature review. Added reference 36. No change to policy statement. Clarification added on FES devices.
11/01/16	Interim Update, approved October 11, 2016. Policy updated with literature review through July 11, 2016; references added/removed/renumbered. Policy statement unchanged.
10/01/17	Annual Review, approved September 21, 2017. Policy moved into new format. Policy updated with literature review through June 22, 2017; reference 1 added. Policy statement unchanged. *This policy varies slightly from the BCBSA Reference Policy.
05/01/18	Annual Review, approved April 18, 2018. Policy updated with literature review through January 2018; no references added. Policy statement unchanged.
08/01/19	Annual Review, approved July 9, 2019. Policy updated with literature review through March 2019. Review of functional electrical stimulation exercise equipment added to policy; this is considered investigational.
08/01/20	Annual Review, approved July 2, 2020. Policy updated with literature review through March, 2020; references added. Policy statements unchanged.
06/01/21	Annual Review, approved May 4, 2021. Policy updated with literature review through January 23, 2021; references added. Policy statements unchanged.
06/01/22	Annual Review, approved May 9, 2022. Policy updated with literature review through January 21, 2022; references added. Policy statements unchanged.
06/01/23	Annual Review, approved May 5, 2023. Policy updated with literature review through February 6, 2023; references added. Minor editorial refinements to policy statements;



Date	Comments
	intent unchanged. Changed the wording from "patient" to "individual" throughout the policy for standardization.
06/01/24	Annual Review, approved May 13, 2024. Policy updated with literature review through January 22, 2024; no references added. Policy statements unchanged.

**Disclaimer:** This medical policy is a guide in evaluating the medical necessity of a particular service or treatment. The Company adopts policies after careful review of published peer-reviewed scientific literature, national guidelines and local standards of practice. Since medical technology is constantly changing, the Company reserves the right to review and update policies as appropriate. Member contracts differ in their benefits. Always consult the member benefit booklet or contact a member service representative to determine coverage for a specific medical service or supply. CPT codes, descriptions and materials are copyrighted by the American Medical Association (AMA). ©2024 Premera All Rights Reserved.

**Scope:** Medical policies are systematically developed guidelines that serve as a resource for Company staff when determining coverage for specific medical procedures, drugs or devices. Coverage for medical services is subject to the limits and conditions of the member benefit plan. Members and their providers should consult the member benefit booklet or contact a customer service representative to determine whether there are any benefit limitations applicable to this service or supply. This medical policy does not apply to Medicare Advantage.





### Discrimination is Against the Law

LifeWise Health Plan of Washington (LifeWise) complies with applicable Federal and Washington state civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. LifeWise does not exclude people or treat them differently because of race, color, national origin, age, disability, sex, gender identity, or sexual orientation. LifeWise provides free aids and services to people with disabilities to communicate effectively with us, such as qualified sign language interpreters and written information in other formats (large print, audio, accessible electronic formats, other formats). LifeWise provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, contact the Civil Rights Coordinator. If you believe that LifeWise has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability, sex, gender identity, or sexual orientation, you can file a grievance with: Civil Rights Coordinator — Complaints and Appeals, PO Box 91102, Seattle, WA 98111, Toll free: 855-332-6396, Fax: 425-918-5592, TTY: 711, Email [AppealsDepartmentInquiries@LifeWiseHealth.com](mailto:AppealsDepartmentInquiries@LifeWiseHealth.com). You can file a grievance in person or by mail, fax, or email. If you need help filing a grievance, the Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights, electronically through the Office for Civil Rights Complaint Portal, available at <https://ocrportal.hhs.gov/ocr/portal/lobby.jsf>, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Ave SW, Room 509F, HHH Building, Washington, D.C. 20201, 1-800-368-1019, 800-537-7697 (TDD). Complaint forms are available at <http://www.hhs.gov/ocr/office/file/index.html>. You can also file a civil rights complaint with the Washington State Office of the Insurance Commissioner, electronically through the Office of the Insurance Commissioner Complaint Portal available at <https://www.insurance.wa.gov/file-complaint-or-check-your-complaint-status>, or by phone at 800-562-6900, 360-586-0241 (TDD). Complaint forms are available at <https://fortress.wa.gov/oic/onlineservices/cc/pub/complaintinformation.aspx>.

### Language Assistance

**ATENCIÓN:** si habla español, tiene a su disposición servicios gratuitos de asistencia lingüística. Llame al 800-817-3056 (TTY: 711).

**注意:** 如果您使用繁體中文，您可以免費獲得語言援助服務。請致電 800-817-3056 (TTY: 711)。

**CHÚ Ý:** Nếu bạn nói Tiếng Việt, có các dịch vụ hỗ trợ ngôn ngữ miễn phí dành cho bạn. Gọi số 800-817-3056 (TTY: 711).

**주의:** 한국어를 사용하시는 경우, 언어 지원 서비스를 무료로 이용하실 수 있습니다. 800-817-3056 (TTY: 711) 번으로 전화해 주십시오.

**ВНИМАНИЕ:** Если вы говорите на русском языке, то вам доступны бесплатные услуги перевода. Звоните 800-817-3056 (телетайп: 711).

**PAUNAWA:** Kung nagsasalita ka ng Tagalog, maaari kang gumamit ng mga serbisyo ng tulong sa wika nang walang bayad. Tumawag sa 800-817-3056 (TTY: 711).

**УВАГА!** Якщо ви розмовляєте українською мовою, ви можете звернутися до безкоштовної служби мовної підтримки.

Телефонуйте за номером 800-817-3056 (телетайп: 711).

**ប្រយ័ត្ន:** បើសិនជាអ្នកនិយាយ ភាសាខ្មែរ, សេវាជំនួយផ្នែកភាសា ដោយមិនគិតលុយ គឺអាចមានសំរាប់អ្នក។ ចូរ ទូរស័ព្ទ 800-817-3056 (TTY: 711)។

**注意事項:** 日本語を話される場合、無料の言語支援をご利用いただけます。800-817-3056 (TTY:711) まで、お電話にてご連絡ください。

**ማስታወሻ:** የሚናገሩት ቋንቋ አማርኛ ከሆነ የትርጉም እርዳታ ድርጅቶች፣ በነጻ ሊያገዝዎት ተዘጋጅተዋል። ወደ ሚከተለው ቁጥር ይደውሉ 800-817-3056 (መስማት ለተሳናቸው: 711)።

**XIYYEEFFANNAA:** Afaan dubbattu Oroomiffa, tajaajjila gargaarsa afaanii, kanfaltiidhaan ala, ni argama. Bilbilaa 800-817-3056 (TTY: 711).

**ملحوظة:** إذا كنت تتحدث اذكر اللغة، فإن خدمات المساعدة اللغوية تتوافر لك بالمجان. اتصل برقم 800-817-3056 (رقم هاتف الصم والبكم: 711).

**ਧਿਆਨ ਦਿਓ:** ਜੇ ਤੁਸੀਂ ਪੰਜਾਬੀ ਬੋਲਦੇ ਹੋ, ਤਾਂ ਭਾਸ਼ਾ ਵਿੱਚ ਸਹਾਇਤਾ ਸੇਵਾ ਤੁਹਾਡੇ ਲਈ ਮੁਫਤ ਉਪਲਬਧ ਹੈ। 800-817-3056 (TTY: 711) 'ਤੇ ਕਾਲ ਕਰੋ।

**ACHTUNG:** Wenn Sie Deutsch sprechen, stehen Ihnen kostenlos sprachliche Hilfsdienstleistungen zur Verfügung. Rufnummer: 800-817-3056 (TTY: 711).

**ໂປດອຸບ:** ຖ້າວ່າ ທ່ານເວົ້າພາສາ ລາວ, ການບໍລິການຊ່ວຍເຫຼືອດ້ານພາສາ, ໂດຍບໍ່ຄ່າສ່ຽງຄ່າ, ຄວນມີພ້ອມໃຫ້ທ່ານ. ໂທ 800-817-3056 (TTY: 711).

**ATANSYON:** Si w pale Kreyòl Ayisyen, gen sévis èd pou lang ki disponib gratis pou ou. Rele 800-817-3056 (TTY: 711).

**ATTENTION:** Si vous parlez français, des services d'aide linguistique vous sont proposés gratuitement. Appelez le 800-817-3056 (ATS : 711).

**UWAGA:** Jezeli mówisz po polsku, możesz skorzystać z bezpłatnej pomocy językowej. Zadzwoń pod numer 800-817-3056 (TTY: 711).

**ATENÇÃO:** Se fala português, encontram-se disponíveis serviços linguísticos, grátis. Ligue para 800-817-3056 (TTY: 711).

**ATTENZIONE:** In caso la lingua parlata sia l'italiano, sono disponibili servizi di assistenza linguistica gratuiti. Chiamare il numero 800-817-3056 (TTY: 711).

**توجه:** اگر به زبان فارسی گفتگو می کنید، تسهیلات زبانی بصورت رایگان برای شما فراهم می باشد. با 800-817-3056 (TTY: 711) تماس بگیرید.